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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/773,691	<b>Applicant(s)</b> SHIDHAM ET AL.	
	<b>Examiner</b> Rene Towa	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. This Office action is responsive to an amendment filed August 3, 2006. Claims 1-37 are pending. Claims 1, 22, 29, 35 and 37 are amended. Claim 38 has been cancelled. No new claim has been added.

#### ***Claim Objections***

2. Claim 37 is objected to because of the following informalities:

at line 1, the limitations "claim 37" render the claim indefinite; for example, the claim depends itself.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 6-8, 16-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US Patent No. 4,967,762) in view of Dann et al. (US Patent No. 2,840,075).

In regards to claim 1, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device comprising:

a hub 40 defining a specimen collection well 62 and mounting a needle 70 having a shaft with an open pointed tip; and

a sample passageway 64 extending from the pointed tip of the needle 70 to a segment inside the hub opening in spaced relation to a floor of the collection well 62 (see figs. 1-2).

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In regards to claim 2, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 defines the entire passageway 64 extending from the pointed tip to a contoured proximal end. (see fig. 2).

In regards to claim 3, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 defines an opening 64 in the floor of the collection well 62 through which the needle shaft extends (see fig. 2).

In regards to claim 6, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the proximal end of the needle 70 in part follows the contour of the collection well 62 (see fig. 2).

In regards to claim 7, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the passageway 64 is defined in part by the needle 70 and in part by an internal channel in the hub 40 (see fig. 2).

In regards to claim 8, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the needle 70 has a straight proximal end disposed at an opening in the hub 40 defining an end of the channel (see fig. 2).

In regards to claim 16, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 includes an outer grip 52 (see figs. 1-2).

In regards to claim 17, DeVries discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device wherein the hub 40 has an open mouth 50 allowing access to the collection well 62 (see fig. 2).

DeVries discloses an apparatus, as described above, that teaches all the limitations of the claims except DeVries does not teach a specimen passageway wherein a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor. However, Dann et al. disclose an apparatus comprising a specimen passageway 30 wherein a specimen can pass through the needle 30 and be deposited in the collection well 28 from above the floor (see figs. 4-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of DeVries with a specimen passageway similar to that of Dann et al. in order to more visibly observe the passage of blood into the collection well (see Dann et al., column 1/line 66 to column 2/line 13; column 2/lines 65-68; column 3/lines 3-9, 14-16 & 33-39).

In regards to claim 19, DeVries as modified by Dann et al. discloses a biopsy device head that teaches all the limitations of the claim except DeVries as modified by Dann et al. does not expressly disclose that the collection well has a volume of at least 100  $\mu$ L. The Examiner takes official notice that changing size is an obvious design choice that has previously been held to be unpatentable, see *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955). As such, it would have been obvious to one of ordinary skill in that art at the time Applicant's invention was made to provide a collection well similar to that of DeVries with a volume of at least 100  $\mu$ L in order to collect a larger sample.

5. Claims 4-5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Dysarz (US Patent No. 6,589,209).

In regards to claims 4-5 and 10-11, Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries as modified by Dann et al. does not teach a needle segment that extends along and opens about a lateral axis at an angle to a longitudinal axis. However, Dysarz discloses a needle aspiration device wherein the proximal end of the needle includes a segment that extends along and opens about a lateral axis at an angle to a longitudinal axis of the needle; wherein the lateral and longitudinal axes are essentially perpendicular (see fig. 21A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with a needle segment similar Devries as modified by Dann et al. with a needle similar to that of Dysarz in order to provide the needle with a safer connection that would resist slippage thereof.

In regards to claim 9, Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries as modified by Dann et al. does not teach a proximal end of the needle that has raised barbs. However, Dysarz discloses a needle aspiration device wherein the proximal end of the needle includes raised barbs (see column 2/lines 18-20). It would have been obvious to one of

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ordinary skill in the art at the time Applicant's invention was made to provide a needle aspiration device with connection similar to that of Dysarz in order to provide the needle with a safer connection that would resist slippage thereof.

6. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Weis-Fogh (US Patent No. 6,284,285).

DeVries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. does not teach a collection well containing an anti-coagulant surface. However, Weis-Fogh discloses a collection bag that containing an anti-coagulant; wherein the anticoagulants include ACD or EDTA (see column 7/lines 46-51). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a collection well similar to that of DeVries as modified by Dann et al. with an anticoagulant similar to that of Weis-Fogh in order to prevent clotting of the sample.

7. Claims 14-15, 18, 22-24, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. (US Patent No. 6,217,556).

In regards to claims 14-15, Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries as modified by Dann et al. does not teach a needle with an anti-friction surface. However, Ellingson et al.

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discloses a biopsy device comprising a needle with an anti-friction surface; wherein the anti-friction surface is a Teflon coating (see column 2/lines 27-29). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Devries as modified by Dann et al. with a coating similar to that of Ellingson et al. in order to reduce friction.

In regards to claim 18, Devries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except Devries as modified by Dann et al. does not teach a lid securable to the hub. However, Ellingson et al. discloses biopsy device comprising a lid 44 securable to a hub 53 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of Devries as modified by Dann et al. with a lid similar to that of Ellingson et al. in order to protect the sterility of the puncture site.

In regards to claims 22 and 36, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

- a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;

- a hub 40 and defining a specimen collection well 62; and

- a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).



In regards to claim 24, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

DeVries as modified by Dann et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. do not teach a valve for controlling an opening in the syringe barrel. However, Ellingson et al. disclose a valve 23 for controlling an opening in a syringe barrel 63 (see fig. 1) and a coupler 35 (see fig. 3A). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that a valve to that of DeVries as modified by Dann et al. with a valve similar to that of Ellingson et al. in order to control the flow of fluid (see Ellingson et al., column 3/lines 17-22).

In regards to claims 35 and 37, DeVries as modified by Dann et al. and Ellingson et al. do not expressly disclose that the collection well has a volume of at least 100  $\mu$ L or more than 500  $\mu$ L. The Examiner takes official notice that changing size is an obvious design choice that has previously been held to be unpatentable, see *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955). As such, it would have been obvious to one of ordinary skill in that art at the time Applicant's invention was made to provide a collection well similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a volume of at least 100  $\mu$ L or more than 500  $\mu$ L in order to collect a larger sample.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Visconti (US Patent No. 5,743,883).

DeVries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. does not teach a sheath stand defining an elongated cavity. However, Visconti discloses biopsy device comprising a sheath stand 24 defining an elongated cavity (see fig. 2). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. with a sheath similar to that of Visconti in order to contain the needle and protect the user from a potential needle stick.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Devries ('762) in view of Dann et al. ('075) further in view of Banys et al. (US Patent No. 5,425,376).

DeVries as modified by Dann et al. discloses a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. does not teach a needle defining a scoop opening at a side of the needle. However, Banys et al. disclose a needle 14 defining a scoop opening 28 at a side of the needle 14 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. with a scoop opening similar to that of Banys et al. in order to assist in severing of a sample of a selected tissue (see Banys et al., column 5/lines 4-8).

10. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Dysarz (US Patent No. 6,589,209).

In regards to claim 26, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 12 has a straight proximal end disposed at an opening in the hub 53 defining an end of the channel (see fig. 2).

DeVries as modified by Dann et al. and Ellingson et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. and Ellingson et al. does not teach a passageway that is defined in part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

In regards to claim 25, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a passageway similar to that of Dysarz since such a modification would amount to a design choice. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

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11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Weis-Fogh ('285).

DeVries as modified by Dann et al. and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Ellingson et al. do not teach a collection well containing an anti-coagulant surface. However, Weis-Fogh discloses a collection bag that containing an anti-coagulant; wherein the anticoagulants include ACD or EDTA (see column 7/lines 46-51). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a collection well similar to that of DeVries as modified by Dann et al. and Ellingson et al. with an anticoagulant similar to that of Weis-Fogh in order to prevent clotting of the sample.

12. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Lo Duca (US Patent No. 4,994,044).

DeVries as modified by Dann et al. and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Ellingson et al. do not teach a sheath stand defining an elongated cavity for containing a needle and having an open end mountable to a hub. However, Lo Duca teaches a system comprising a sheath stand 60' defining an elongated cavity for containing a

needle and having an open end 62 mountable to a hub (see figs. 3-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a sheath stand similar to that of Lo Duca in order to avoid sticking the needle into the finger of the operator (see Lo Duca, column 3/lines 49-54).

13. Claims 29-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Ellingson et al. ('556) even further in view of Banys et al. ('376).

In regards to claim 29, DeVries as modified by Dann et al. and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Ellingson et al. do not teach a a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. and Ellingson et al. with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

In regards to claim 30, DeVries as modified by Dann et al. and Ellingson et al. disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Ellingson et al. do not teach a scoop opening. However, Banys et al.

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teach a scoop opening in the needle. However, Banys et al. disclose a needle 14 defining a scoop opening 28 at a side of the needle 14 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that DeVries as modified by Dann et al. and Ellingson et al. with a scoop opening similar to that of Banys et al. in order to assist in severing of a sample of a selected tissue (see Banys et al., column 5/lines 4-8).

14. Claims 22-24, and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham (US Patent No. 4,549,554).

In regards to claims 22 and 36, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device, comprising:

- a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;
- a hub 40 and defining a specimen collection well 62; and
- a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;

wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

In regards to claim 24, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 70 defines the entire passageway extending from the pointed tip to a contoured proximal end (see figs. 1-2).

In regards to claim 31, DeVries as modified by Dann et al. discloses a method as follows:

- inserting the needle 70 into a specimen sample site;
- communicating a vacuum to the needle 70;
- probing the specimen sample site with the needle 70 to collect specimens in the collection well of the hub 40;
- releasing the vacuum in the needle 70;
- withdrawing the needle 70 from the specimen sample site;
- separating the hub from the device; and
- transferring specimens collected in the hub to an examination site (see DeVries, column 1/lines 55-72; column 2/lines 3-12; column 3/lines 1-3 & 8-14).

DeVries as modified by Dann et al. teach a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. does not teach creating a vacuum by closing a valve and pulling a piston. However, Markham teaches a method as follows:

In regards to claim 31, Markham discloses a method of needle aspiration biopsy using a device as recited in claim 22, comprising the steps of:

- creating a vacuum in the syringe 10;
- inserting the needle 36 into a specimen sample site;
- communicating the vacuum to the needle 36 (see figs. 1-2);
- probing the specimen sample site with the needle 36 to collect specimens in the collection well of the hub;

releasing the vacuum in the needle 36;  
withdrawing the needle 36 from the specimen sample site;  
separating the hub from the device; and  
transferring specimens collected in the hub to an examination site (see figs. 1-2)  
column 4/lines 23-28, 37-43 & 59-64).

In regards to claim 32, Markham discloses a method of needle aspiration biopsy wherein the step of creating a vacuum in the syringe 10 includes closing the valve 28 and pulling the syringe piston 22 away from the syringe barrel 12 (see column 4/lines 23-28).

In regards to claim 33, Markham discloses a method of needle aspiration biopsy wherein the vacuum is communicated to the needle 36 by opening the valve 28 (see column 4/lines 37-43).

In regards to claim 34, Markham discloses a method of needle aspiration biopsy wherein the step of releasing the vacuum in the needle 36 includes reclosing the valve 28 (see column 4/lines 59-64).

DeVries as modified by Dann et al. disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. do not teach a valve for controlling an opening in the syringe barrel. However, Markham disclose a valve 28 for controlling an opening in a syringe barrel 63 and a coupler 34 (see figs. 1-2). Since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of



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ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. with a stopcock valve similar to that of Markham in order to control the flow of fluid to the syringe barrel as is well known in the art (see Markham, figs. 1-2).

In regards to claims 35 and 37, DeVries as modified by Dann et al. and Markham do not expressly disclose that the collection well has a volume of at least 100  $\mu$ L or more than 500  $\mu$ L. The Examiner takes official notice that changing size is an obvious design choice that has previously been held to be unpatentable, see *In re Rose*, 220 F.2d 459, 463, 105 USPQ 237, 240 (CCPA 1955). As such, it would have been obvious to one of ordinary skill in that art at the time Applicant's invention was made to provide a collection well similar to that of DeVries as modified by Dann et al. and Markham with a volume of at least 100  $\mu$ L or more than 500  $\mu$ L in order to collect a larger sample.

15. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Dysarz (US Patent No. 6,589,209).

In regards to claim 26, DeVries as modified by Dann et al. disclose a high specimen yielding anti-reflux needle aspiration biopsy device wherein the needle 12 has a straight proximal end disposed at an opening in the hub 53 defining an end of the channel (see fig. 2).

DeVries as modified by Dann et al. and Markham disclose a system, as described above, that teaches all the limitations of the claims except DeVries as modified by Dann et al. and Markham does not teach a passageway that is defined in

part by a needle and an internal channel in the hub. However, Dysarz discloses a system as follows:

In regards to claim 25, Dysarz discloses a system wherein a passageway is defined in part by the needle 39 and in part by an internal channel 20 in the hub 48 (see figs. 1 & 18-19).

It would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Markham with a passageway similar to that of Dysarz since such a modification would amount to a design choice. It has previously been held that merely changing aesthetic design is not patentable--See *In re Seid*, 161 F.2d 229, 231, 73 USPQ 431, 433 (CCPA 1947).

16. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Weis-Fogh ('285).

DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Markham do not teach a collection well containing an anti-coagulant surface. However, Weis-Fogh discloses a collection bag that containing an anti-coagulant; wherein the anticoagulants include ACD or EDTA (see column 7/lines 46-51). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a collection well similar to that of DeVries as modified by Dann et al. and

Markham with an anticoagulant similar to that of Weis-Fogh in order to prevent clotting of the sample.

17. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Lo Duca (US Patent No. 4,994,044).

DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Markham do not teach a sheath stand defining an elongated cavity for containing a needle and having an open end mountable to a hub. However, Lo Duca teaches a system comprising a sheath stand 60' defining an elongated cavity for containing a needle and having an open end 62 mountable to a hub (see figs. 3-5). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of DeVries as modified by Dann et al. and Markham with a sheath stand similar to that of Lo Duca in order to avoid sticking the needle into the finger of the operator (see Lo Duca, column 3/lines 49-54).

18. Claims 29-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Dann et al. ('075) further in view of Markham ('554) even further in view of Banys et al. ('376).

In regards to claim 29, DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified

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by Dann et al. and Markham do not teach a piston lock. However, Banys et al. teach a piston lock 42 mounted to the syringe so as to hold the position of the piston relative to the barrel (see figs. 5-6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that of DeVries as modified by Dann et al. and Markham with a piston lock similar to that of Banys et al. in order to hold the plunger in the fully inserted position within the syringe (see column 2/lines 63-65; column 4/lines 34-38).

In regards to claim 30, DeVries as modified by Dann et al. and Markham disclose a high specimen yield anti-reflux head for a needle aspiration biopsy device, as described above, that teaches all the limitations of the claim except DeVries as modified by Dann et al. and Markham do not teach a scoop opening. However, Banys et al. teach a scoop opening in the needle. However, Banys et al. disclose a needle 14 defining a scoop opening 28 at a side of the needle 14 (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a biopsy device similar to that DeVries as modified by Dann et al. and Markham with a scoop opening similar to that of Banys et al. in order to assist in severing of a sample of a selected tissue (see Banys et al., column 5/lines 4-8).

### ***Response to Arguments***

19. Applicant's arguments filed August 3, 2006 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

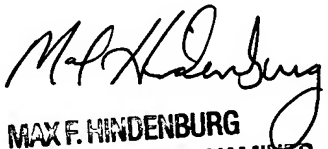
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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RTT

  
MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700